

In the United States Court of Federal Claims

No. 10-489V

(Filed Under Seal: February 26, 2014)

(Reissued for Publication: March 21, 2014)¹

VALERIA FLORES,

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Petitioner,

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v.

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SECRETARY OF HEALTH AND
HUMAN SERVICES,

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Respondent.

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Vaccine Act; Motion for Review; HPV
Vaccine; Spinal Cord Stroke; Althen;
Causation-in-Fact; Burden of Proof; Genetic
Susceptibility; Medical Literature;
Unknown Etiology; Logical Sequence of
Cause and Effect

Clifford J. Shoemaker, Vienna, VA, for petitioner.

Debra A. Filteau Begley, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

SWEENEY, Judge

Petitioner seeks compensation under the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”), 42 U.S.C. §§ 300aa-1 to -34 (2006), alleging that she sustained a spinal cord stroke caused by a human papillomavirus (“HPV”) vaccination. In a September 28, 2013 decision, the special master denied petitioner’s request for compensation. Before the court is petitioner’s motion for review of the special master’s decision. For the reasons set forth below, the court denies petitioner’s motion for review and sustains the decision of the special master.

¹ Vaccine Rule 18(b), contained in Appendix B of the Rules of the United States Court of Federal Claims, affords each party fourteen days in which to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute “a clearly unwarranted invasion of privacy.” Neither party objected to the public disclosure of any information contained in this opinion.

I. BACKGROUND

A. Medical History

Petitioner's medical history is not in dispute, and can be briefly summarized.² On April 28, 2008, when she was fourteen years old, petitioner received her first HPV vaccination. She received her second HPV vaccination on June 27, 2008. The following day, she began to experience several symptoms, including left-sided weakness, severe headache, and shortness of breath. She then developed flaccid paralysis of her extremities and slurred speech. When the emergency medical service arrived at her house, petitioner developed bradycardia and suffered a cardiac arrest. She was taken to the emergency room at Mt. Sinai Hospital, and was subsequently transferred to Rush University Medical Center ("Rush").

At Rush, petitioner underwent an extensive medical workup and was given a working diagnosis of transverse myelitis. That diagnosis changed after two neurologists, Drs. Tilwalli and Stefofski, examined petitioner on August 6, 2008. As described by the special master:

Dr. Tilwalli, a neurology fellow, opined that given Valeria's quick onset, absence of inflammatory markers, and lack of response to anti-inflammatory treatment, he favored a vascular etiology. He also noted that he thought Valeria's HPV vaccination was too close to symptom onset to induce an inflammatory response. Similarly, a neurologist, Dr. Stefofski, opined that Valeria's quick symptom onset "strongly favors a vascular etiology over immune mediated/inflammatory (definitely too soon for Gardasil or even for a remote preceding myelitogenic trigger)." He also noted that due to the lack of response to corticosteroids and cyclophosphamide, he doubted an autoimmune etiology.

Flores, 2013 WL 5587390, at *4 (citations omitted). Ultimately, it was determined that petitioner had experienced a spinal cord stroke.

On August 7, 2008, petitioner was transferred from Rush to the Rehabilitation Institute of Chicago. Her physical condition did not improve; she continued to require total assistance for mobility and all activities of daily living. In addition, she had been on continuous ventilation during her stay at Rush and remained on the ventilator during her rehabilitation. Petitioner was discharged from inpatient rehabilitation on December 16, 2008. Since that time, she has shown some improvement—she has begun to feel some sensation in her extremities and exhibited voluntary movement in two fingers. However, she remains dependent on a ventilator.

² The court derives petitioner's undisputed medical history from the special master's decision. See generally Flores v. Sec'y of HHS, No. 10-489V, 2013 WL 5587390, at *3-5 (Fed. Cl. Spec. Mstr. Sept. 12, 2013).

B. Procedural History

Petitioner's father filed a petition for compensation under the Vaccine Act on July 29, 2010, claiming that the HPV vaccine caused his daughter's spinal cord stroke. Upon reaching the age of majority, Ms. Flores was substituted as petitioner. After the submission of medical records and expert reports, the special master convened an evidentiary hearing, during which he heard the testimony of three expert witnesses. Petitioner offered the testimony of neurologist Douglas A. Kerr, M.D., Ph.D., and respondent offered the testimony of pediatric neurologist Peter M. Bingham, M.D., and pediatric hematologist Joan Cox Gill, M.D. Posthearing briefs were filed, and the special master issued a decision on September 12, 2013.

In his decision, the special master noted that all three experts agreed that petitioner had suffered a spinal cord stroke, which was caused by a blood clot that had become lodged in a spinal cord vessel, depriving petitioner's spinal cord of oxygen and causing permanent injury. Where the experts disagreed, the special master explained, was on the cause of the blood clot. Dr. Kerr opined that the blood clot was caused by the HPV vaccine. Specifically, he asserted that petitioner had a genetic predisposition to blood clotting involving multiple genes; that petitioner's first HPV vaccination sensitized her immune system; that the second HPV vaccination elicited an exuberant, rapid immune response; and that the immune response resulted in petitioner's blood clot, either through inflammation or platelet aggregation. Drs. Bingham and Gill, on the other hand, found it improbable that the HPV vaccine could be connected to petitioner's blood clot. Dr. Bingham explained that there was neither clinical evidence of inflammation, nor a noted connection between the HPV vaccine and spinal cord strokes or blood clots. Dr. Gill asserted that there was no clinical evidence of inflammation or platelet aggregation, and that a clotting response via inflammation would have taken at least four days to develop.

The special master initially found that petitioner was unable to establish that she had a genetic predisposition to blood clotting. Because this genetic predisposition was a critical factor of the theory of causation advanced by Dr. Kerr, the special master concluded that petitioner could not establish that Dr. Kerr's theory was probable. Although this conclusion, on its own, was sufficient to deny petitioner's request for compensation under the Vaccine Act, the special master addressed other aspects of Dr. Kerr's theory. First, he noted that Dr. Kerr's theory was premised on petitioner's spinal cord stroke originating from a blood clot in a vein (venous thrombosis), but that the evidence supported a finding that the blood clot originated in an artery (arterial thrombosis). Second, the special master held that petitioner failed to demonstrate that the HPV vaccine can contribute to the type of inflammation that causes blood clots and strokes or that petitioner's second HPV vaccination did contribute to her blood clot or stroke. Similarly, the special master concluded that petitioner had not shown that she had experienced platelet aggregation or that any platelet aggregation contributed to her blood clot or stroke.

In addition to addressing specific elements of Dr. Kerr's theory of causation, the special master discussed some of the medical literature submitted by the parties. He held that the Slade

article, relied upon heavily by Dr. Kerr, did not offer “significant support” for the proposition that the HPV vaccine can contribute to strokes. The special master also concluded that other medical literature added “slightly” to the reasons to reject Dr. Kerr’s theories of causation.

At the close of his decision, after concluding that the lack of an identifiable cause of petitioner’s spinal cord stroke did not offer “significant support” for her theory that the HPV vaccine caused the stroke, the special master analyzed petitioner’s case under the test for causation set forth in Althen v. Secretary of HHS, 418 F.3d 1274 (Fed. Cir. 2005). In Althen, the United States Court of Appeals for the Federal Circuit (“Federal Circuit”) articulated a three-part test, based on prior precedent, explaining what a petitioner must show to prove causation under the Vaccine Act:

[Petitioner]’s burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1278. The special master concluded that petitioner had not established either of the first two prongs of the Althen test, explaining that petitioner had not shown, more probably than not, that the HPV vaccine could contribute to spinal cord strokes or that the HPV vaccination petitioner received on June 27, 2008, did cause her stroke. The special master also noted that the timing of petitioner’s stroke was evidence that it was not caused by the HPV vaccine. Remarking that this was not a close case, the special master held that petitioner had not met her burden of proving that the HPV vaccine caused her stroke. He therefore denied petitioner’s request for compensation. Petitioner, alleging error, seeks review of the special master’s decision, which respondent opposes. The court heard argument on the parties’ competing positions on February 26, 2014.³

II. DISCUSSION

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master, and upon such review, may:

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,

³ During the February 26, 2014 proceedings, petitioner advanced several arguments that were not raised in her motion for review. These arguments are waived and the court will not address them. See L-3 Commc’ns EOTech, Inc. v. United States, 87 Fed. Cl. 656, 659 n.2 (2009) (“Plaintiff must not be allowed to advance new legal theories at oral argument, prejudicing defendant.”); see also SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312, 1319 (Fed. Cir. 2006) (“[A]rguments not raised on the opening brief are waived.”).

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2). In the instant case, petitioner enumerates, pursuant to Vaccine Rule 24, three objections to the special master's decision. First, petitioner asserts that the special master impermissibly required her to identify the specific genes or cluster of genes that could have caused her susceptibility to blood clotting. Second, petitioner contends that the special master abused his discretion by rejecting several aspects of Dr. Kerr's testimony regarding the logical sequence of cause and effect that connected her second HPV vaccination to her spinal cord stroke. Third, petitioner avers that the special master held her to an elevated burden of proof that was rejected in Althen and was therefore not in accordance with the law. All three objections relate to whether the special master properly held that petitioner had not established that the HPV vaccine caused her spinal cord stroke.

A. Proving Causation Under the Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if a petitioner proves, by a preponderance of evidence, all of the elements set forth in 42 U.S.C. § 300aa-11(c)(1),⁴ and if there is not a preponderance of evidence that the illness is due to factors unrelated to the administration of the vaccine. A petitioner can recover in one of two ways: either by proving an injury listed on the Table or by proving causation-in-fact. See 42 U.S.C. §§ 300aa-11(c)(1)(C), -13(a)(1). Under the first method of recovery, a petitioner must demonstrate that the injury was sustained within the time frame set forth in the Table. Id. § 300aa-11(c)(1)(C)(I), -14(a). "If petitioner can make such a showing, causation is presumed and petitioner is deemed to have made out a prima facie case of entitlement to compensation under the Act." Whitcotton v. Sec'y of HHS, 81 F.3d 1099, 1102 (Fed. Cir. 1996).

To establish a prima facie case when proceeding on a causation-in-fact theory, as petitioner attempted to do in this case, a petitioner must "prove, by a preponderance of the

⁴ Subsection (c)(1) requires, among other things, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Vaccine Injury Table ("Table"); (2) that the vaccine was received in the United States or in its trust territories; (3) that the injured person either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine that resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury or death. 42 U.S.C. § 300aa-11(c)(1).

evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999). “[T]o show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show ‘a medical theory causally connecting the vaccination and the injury.’” Id. at 1352-53 (quoting Grant v. Sec’y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (per curiam)). In other words, “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury,’” id. at 1353 (quoting Grant, 956 F.2d at 1148), and “[t]his ‘logical sequence of cause and effect’ must be supported by a sound and reliable medical or scientific explanation,” Knudsen v. Sec’y of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994) (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993); Jay v. Sec’y of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993)); see also 42 U.S.C. § 300aa-13(a)(1) (“The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.”). However, medical or scientific certainty is not required. Knudsen, 35 F.3d at 548-49; Bunting v. Sec’y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991).

As noted above, the Federal Circuit, in Althen, distilled this prior precedent into a three-part test, holding that to prove causation-in-fact, a petitioner must provide “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” 418 F.3d at 1278. All three prongs “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford v. Sec’y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

Once a petitioner has established a prima facie case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995); de Bazan v. Sec’y of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec’y of HHS, 991 F.2d 1570, 1575 (Fed. Cir. 1993). Regardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case. See Stone v. Sec’y of HHS, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan, 539 F.3d at 1353 (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case-in-chief.”).

B. Allegations That Portions of the Special Master’s Decision Were Not in Accordance With the Law

Within her enumerated objections to the special master’s decision, petitioner contends that several of the special master’s conclusions were not in accordance with the law.

Specifically, she argues that the special master, in various portions of his decision, required her to provide “objective confirmation in the medical community” linking her second HPV vaccination to her spinal cord stroke, impermissibly elevating her burden beyond what is permitted by the Vaccine Act. Mot. 16.

1. Genetic Susceptibility

Petitioner first asserts that the special master improperly elevated her burden of proof by requiring her to identify the specific genes or cluster of genes that made her susceptible to a vaccine injury. In his decision, the special master noted that Dr. Kerr’s theory of causation depended on petitioner being genetically susceptible to blood clotting, and that Dr. Kerr testified that such a genetic predisposition would involve a combination of several genes. However, Dr. Kerr was unable to identify what genes or gene combination would be involved. In addition, Dr. Kerr acknowledged that a gene mutation discovered during petitioner’s workup at Rush—a MTHFR1298C heterozygous mutation—could not, by itself, cause susceptibility to blood clotting or stroke, and that the MTHFR gene might not have been part of the gene cluster at all. Indeed, remarked the special master, Dr. Gill, a hematologist, explained that petitioner’s MTHFR gene mutation does not cause blood clotting, and that there was no clinical evidence of petitioner having other MTHFR gene mutations that might increase the risk of blood clots. Based on all of this testimony, the special master concluded that Dr. Kerr’s assertion that petitioner must have had a cluster of genes causing a predisposition to blood clotting was no more than mere speculation, and was therefore insufficient to meet petitioner’s burden of establishing a probable theory of causation.

A close examination of the special master’s analysis reveals that he did require petitioner to offer proof of the specific genes or gene cluster that contributed to petitioner’s predisposition to blood clotting. See, e.g., Flores, 2013 WL 5587390, at *8 (“Dr. Kerr acknowledged that he did not know what that combination of genes might be. In the final analysis, I conclude that Dr. Kerr was engaging in mere speculation or guesswork in concluding that Valeria must have had such a cluster of genes. Thus, this part of his theory . . . has not been shown to be probable.” (citation omitted)), *9 (“I find that Dr. Kerr totally failed to establish . . . that Valeria had some type of genetic predisposition that made her susceptible to have blood clots. . . . [H]e could do no more than propose that Valeria might have had a cluster of several different genes that made her susceptible, but could not even propose what any of those genes might have been.”). The special master was incorrect to do so.

Under the second prong of the Althen test, petitioner must show a logical sequence of cause and effect connecting her second HPV vaccination to her spinal cord stroke. In making this showing, she cannot be required to prove “the presence of . . . genetic disposition” because such a requirement is “inconsistent with allowing ‘the use of circumstantial evidence envisioned by the preponderance standard’” and therefore “impermissibly raises [her] burden under the Vaccine Act” Capizzano v. Sec’y of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (quoting Althen, 418 F.3d at 1280). Thus, while direct evidence of genetic susceptibility is probative, in

the absence of such direct evidence, petitioner was entitled to demonstrate genetic susceptibility through medical opinion. Id. at 1326. Therefore, requiring petitioner to identify the specific genes or gene cluster that contributed to her purported blood clotting predisposition is contrary to law. Nevertheless, this error is not dispositive. As the court explains later in this decision, because the special master correctly concluded that petitioner failed to establish other aspects of the causation theory advanced by Dr. Kerr, she cannot demonstrate entitlement to compensation under the Vaccine Act.

2. Medical Literature

Another portion of the special master's decision that was contrary to law, asserts petitioner, is the special master's review of and reliance on medical literature. Specifically, she contends that although the special master stated that he was not requiring her to submit medical literature, he improperly used the submitted medical literature showing that there was no association between the HPV vaccine and her injury to "bolster the weight of evidence" against her. Mot. 15. According to petitioner, this practice was rejected by the Federal Circuit in Althen and Capizzano. Upon reviewing the special master's decision, however, the court discerns no error.

In Althen and Capizzano, the Federal Circuit merely held that a special master could not require a petitioner to submit medical literature to prove causation. Capizzano, 440 F.3d at 1324; Althen, 418 F.3d at 1280. In neither case did the Federal Circuit preclude, much less discuss, a special master's review and use of medical literature submitted by the parties on their own volition. In fact, in Andreu v. Secretary of HHS, the Federal Circuit remarked:

Although Althen and Capizzano make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. Althen makes clear that a claimant's theory of causation must be supported by a "reputable medical or scientific explanation." The assessment of whether a proffered theory of causation is "reputable" can involve assessment of the relevant scientific data.

569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (citations omitted). In his decision, the special master thoroughly evaluated the Slade article, which was submitted by both parties in support of their respective positions, and concluded that it did not provide "significant support for Dr. Kerr's general proposition that the HPV vaccine [could] contribute to causing strokes." Flores, 2013 WL 5587390, at *13-15. The special master then addressed other medical literature in the record—specifically the Gold and Gee articles—and determined that it "add[ed] slightly to the reasons for rejecting Dr. Kerr's causation theory." Id. at *16. There is no indication that the special master required petitioner to provide medical literature supporting Dr. Kerr's causation theory; indeed, the special master clearly recognized that medical literature or epidemiological

evidence was not required to prove causation. Thus, under binding Federal Circuit precedent, it was not legally improper for the special master to consider the articles submitted by the parties and determine whether they supported or detracted from the theory of causation advanced by Dr. Kerr.

3. Unknown Etiology of Petitioner's Injury

The third portion of the special master's decision challenged by petitioner as contrary to law is the special master's discussion of the lack of evidence supporting an alternative cause for her injury. Petitioner contends that this lack of evidence is only relevant to respondent's burden of establishing an alternative cause, and not to Dr. Kerr's theory of causation. Petitioner is mistaken.

As noted above, a special master may consider the existence of alternative causes of injury in determining whether the petitioner has established a prima facie case of causation. See Stone, 676 F.3d at 1379; de Bazan, 539 F.3d at 1353. Here, the special master noted that neither the medical records, nor respondent's experts, identified a known cause of petitioner's spinal cord stroke. He therefore inquired whether the lack of evidence of a known cause supported Dr. Kerr's theory that petitioner's second HPV vaccination caused her stroke. Upon reviewing the evidence in the record, the special master concluded that because it was "common for the cause of spinal cord strokes not to be identified," the fact that the cause of petitioner's stroke was not identified did not make Dr. Kerr's theory more tenable. Flores, 2013 WL 5587390, at *17. As the unambiguous Federal Circuit precedent makes clear, the special master did not err in considering evidence related to an alternative cause in determining whether petitioner had met her burden of proof of causation.

C. Allegations That the Special Master Abused His Discretion

In addition to arguing that parts of the special master's decision were contrary to law, petitioner contends that the special master abused his discretion in rejecting Dr. Kerr's testimony regarding certain elements of the logical sequence of cause and effect that allegedly connected her second HPV vaccination to her spinal cord stroke; namely, the origin of her blood clot and the existence of inflammation and platelet aggregation. An abuse of discretion occurs when a "decision is based on clearly erroneous findings of fact, is based on erroneous interpretations of the law, or is clearly unreasonable, arbitrary or fanciful." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc); accord Hendler v. United States, 952 F.2d 1364, 1380 (Fed. Cir. 1991) ("An abuse of discretion may be found when (1) the court's decision is clearly unreasonable, arbitrary, or fanciful; (2) the decision is based on an erroneous conclusion of the law; (3) the court's findings are clearly erroneous; or (4) the record contains no evidence upon which the court rationally could have based its decision."), quoted in Murphy v. Sec'y of HHS, 30 Fed. Cl. 60, 61 (1993). It is well settled that under this standard, the court accords

deference to the special master's factual findings and fact-based conclusions.⁵ It is not the court's role to reweigh the evidence. See Hodges v. Sec'y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993) (“[O]n review, the Court of Federal Claims is not to second guess the Special Master[']s fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process. . . . That level of deference is especially apt in a case in which the medical evidence of causation is in dispute.”). Despite this unambiguous standard, a review of petitioner's contentions reveals that this is precisely what petitioner is asking the court to do—reweigh the evidence.

1. The Origin of Petitioner's Blood Clot

Petitioner first contends that the special master abused his discretion by rejecting Dr. Kerr's testimony that her spinal cord stroke originated from a venous thrombosis in favor of Dr. Gill's testimony that her stroke originated from an arterial thrombosis. In support of this contention, petitioner notes that Dr. Kerr has more experience than Dr. Gill with spinal cord strokes and avers that Dr. Gill relied on the results of a test—the D-dimer test—that do not support her position. Accordingly, petitioner argues, the special master's conclusion that Dr. Gill was more persuasive on the origin of the blood clot was improper.

While petitioner's first point—that Dr. Kerr was more experienced than Dr. Gill regarding spinal cord strokes—may be true, it is only one aspect of what the special master could have considered in analyzing the origins of petitioner's blood clot. Indeed, the special master's decision reflects that he considered the testimony of all three experts regarding the bases for their respective positions, as well as a medical article that supported Dr. Gill's position. That the special master assigned different weights to this evidence than the weights preferred by petitioner is not an abuse of discretion.

Petitioner's second point concerns the results of three D-dimer tests she underwent at Rush on July 5 and 6, 2008. According to the undisputed testimony of Dr. Gill, the D-dimer test shows whether there is ongoing coagulation, and a negative result suggests that a venous thrombosis is highly unlikely. The reference range for petitioner's D-dimer tests was “0.00 - 0.60 ug/mL,” and appended to the results of each test was the following comment: “D-Dimer results of less than 0.5 ug/mL have been shown to contribute to the exclusion of venous

⁵ There is abundant precedent from the Federal Circuit to this effect. See, e.g., Whitecotton, 81 F.3d at 1108 (“Congress desired the special masters to have very wide discretion with respect to the evidence they would consider and the weight to be assigned that evidence.”); Munn v. Sec'y of HHS, 970 F.2d 863, 871 (Fed. Cir. 1992) (emphasizing that “the probative value of the evidence” and “the credibility of the witnesses” were within the special master's purview as fact finder); Hines v. Sec'y of HHS, 940 F.2d 1518, 1527 (Fed. Cir. 1991) (“[A]rguments as to the weighing of evidence, particularly where, as here, witness credibility is involved, do not demonstrate reversible error.”).

thromboembolism with a negative predictive value of approximately 98% when results are used as part of the total clinical evaluation of the patient.” Pet’r’s Ex. 20 at 928-32. The results of petitioner’s three D-dimer tests were 0.51 ug/mL, 0.46 ug/mL, and 0.49 ug/mL. Id. Dr. Gill testified that these test results made it “very unlikely” that petitioner suffered from a venous thrombosis. Tr. 164.

Petitioner advances two arguments related to the D-dimer test results: (1) Dr. Gill’s testimony was contradicted by the comment in the test results, and (2) Dr. Gill acknowledged that petitioner was taking medication that could lower the test results. Petitioner’s first argument suffers from an error in logic. Petitioner contends that the 0.51 ug/mL test result contradicts Dr. Gill’s testimony because it does not meet the “less than 0.5 ug/mL” threshold described in the test result comment.⁶ However, the fact that test results that are less than 0.5 ug/mL may help exclude the existence of a venous thrombosis with 98% certainty does not mean that test results that are greater than 0.5 ug/mL reflect the existence of a venous thrombosis. Rather, the more logical conclusion is that a test result that is greater than 0.5 ug/mL, but still within the reference range, may help exclude the existence of a venous thrombosis, but with less than 98% certainty. This interpretation is supported by Dr. Gill’s characterization of petitioner’s D-dimer test results as “negative,” id., and “within the normal range,” id. at 182-84. Thus, the comment in the D-dimer test results does not contradict Dr. Gill’s testimony as petitioner contends.

Petitioner’s second argument fares no better. While Dr. Gill acknowledged that one of petitioner’s medications could lower the D-dimer test results, she did not retract her conclusion that the test results made a venous thrombosis unlikely. As a result, the record contains evidence that supports the special master’s reliance on Dr. Gill’s analysis of the D-dimer test results. Petitioner therefore has not demonstrated that the special master’s acceptance of Dr. Gill’s testimony was an abuse of discretion. Instead, all that she has established is that she would weigh the evidence regarding the effect of petitioner’s medication on the D-dimer test results differently.

In sum, the special master’s conclusion that Dr. Gill was more persuasive than Dr. Kerr regarding the origin of petitioner’s blood clot was not improper.

2. Inflammation and Platelet Aggregation

In addition to arguing that the special master should not have rejected Dr. Kerr’s testimony that she experienced a venous thrombosis, petitioner contends that the special master abused his discretion in rejecting Dr. Kerr’s testimony regarding how the immune response triggered by her second HPV vaccination led to a blood clot, and instead accepting the testimony of Dr. Gill.

⁶ Petitioner does not address the other two D-dimer test results in her motion for review.

Dr. Kerr proposed two mechanisms that might link petitioner's immune response to her blood clot: inflammation and platelet aggregation. With respect to inflammation, petitioner asserts that Dr. Kerr's theory relied upon the presence of localized inflammation, i.e., inflammation in her central nervous system, and that Dr. Gill rejected Dr. Kerr's theory because (1) there was no evidence of systemic inflammation in her test results and (2) her spinal cord stroke occurred too soon after her second HPV vaccination. Petitioner contends that the special master's acceptance of Dr. Gill's testimony over the testimony of Dr. Kerr was improper because Dr. Gill was looking for systemic inflammation based on an incorrect diagnosis of her neurological injury, and because the timing of her stroke was appropriate because her immune system was primed by her first HPV vaccination. She further contends, with respect to platelet aggregation, that the special master improperly required her to prove a specific biological mechanism of injury.⁷

Ultimately, Dr. Gill's characterization of petitioner's injury and the possible priming effect of petitioner's first HPV vaccination were not material to the special master's decision to reject Dr. Kerr's testimony. Not only did Dr. Gill and Dr. Bingham testify that none of petitioner's test results reflected systemic inflammation, Dr. Bingham further testified that the results of tests of petitioner's spinal cord fluid did not show inflammation, i.e., there was no evidence of localized inflammation. Moreover, Dr. Gill testified that there was no evidence of platelet aggregation in petitioner's test results. The special master was therefore entitled to conclude that if the logical sequence of cause and effect posited by Dr. Kerr included the existence of inflammation or platelet aggregation, but there was no evidence of inflammation or platelet aggregation in any of petitioner's test results, then petitioner could not establish an essential element of causation linking her second HPV vaccination to her spinal cord stroke.

The court's conclusion finds ample support in Federal Circuit precedent. See, e.g., Moberly v. Sec'y of HHS, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (noting that "the special master is entitled to require some indicia of reliability to support the assertion of the expert witness" and holding that the special master did not err in rejecting the petitioner's theory of causation when petitioner's expert could not identify any evidence that the mechanism underlying his theory was at work in the petitioner's case); see also Capizzano, 440 F.3d at 1327 ("A claimant could satisfy the first and third prongs [of the Althen test] without satisfying the second prong when medical records and medical opinion do not suggest that the vaccine caused the injury . . ."). The Federal Circuit's decision in Stone is particularly instructive. In that case, the injured children suffered from Severe Myoclonic Epilepsy of Infancy, a seizure disorder. Stone, 676 F.3d at 1374. The theory of causation proposed by the petitioners' expert was that the vaccine at issue caused a fever, triggering initial febrile seizures, which caused lasting brain injury, leading to the seizure disorder. Id. at 1376, 1384. The special master concluded that there was no evidence that the children suffered brain damage as a result of the initial seizures. Id. at 1384. In rejecting the petitioners' argument that the special master improperly required them to prove a biological

⁷ Petitioner did not raise this argument with respect to Dr. Kerr's proposed mechanism of inflammation.

mechanism of causation, the Federal Circuit remarked: “[T]he special master did not insist on evidence of the biological mechanism by which the brain damage was caused. He merely sought evidence of the existence of brain damage—a key component of [the expert’s] theory—and [the expert] was unable to provide any.” *Id.* at 1385. Noting that the special master concluded that the expert’s “inference of brain damage, in the face of clinical records showing no brain damage, was unpersuasive and . . . therefore insufficient to carry the petitioners’ burden on causation,” the Federal Circuit explained that the special master had “denied compensation not because the parties failed to show how the vaccines caused brain damage, but because they failed to show that the vaccines caused any brain damage.” *Id.* at 1384. Similarly here, the special master denied petitioner compensation because she failed to show that her second HPV vaccination actually did lead to a blood clot, either through inflammation or platelet aggregation. This was not an abuse of discretion.

D. Application of the Althen Test

The theory of causation advanced by Dr. Kerr was that petitioner had a genetic predisposition to blood clotting involving multiple genes; that petitioner’s first HPV vaccination sensitized her immune system; that the second HPV vaccination elicited an exuberant, rapid immune response; that the immune response resulted in the blood clot, either through the creation of inflammation or platelet aggregation; and that the blood clot caused petitioner’s spinal cord stroke. To establish the second prong of the Althen test—a logical sequence of cause and effect connecting the vaccine to the injury—petitioner was required to demonstrate each link in this causative chain by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1). The court concluded that the special master improperly required petitioner to provide specific proof of genetic susceptibility to blood clotting. However, the special master’s rejection of Dr. Kerr’s testimony regarding inflammation and platelet aggregation, which the court concluded was not an abuse of discretion, leads the court to find that petitioner was unable to establish another link in the causative chain—the link between the immune response triggered by her second HPV vaccination and her blood clot. Thus, the special master’s determination that petitioner was not entitled to compensation under the Vaccine Act because she did not establish that the HPV vaccine caused her spinal cord stroke must be upheld.

III. CONCLUSION

For the reasons stated above, the court **DENIES** petitioner’s motion for review and **SUSTAINS** the decision of the special master. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Judge